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(71) Applicant (for all designated States except US): MAL-LINCKRODT MEDICAL, INC. [US/US]; 675 McDonnell Blvd., P.O. Box 5840, St. Louis, MO 63134

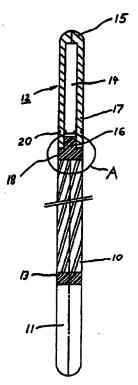
(US). With international search report.

(72) Inventor; and
(75) Inventor/Applicant (for US only): BORNEMAN, Wim
[NL/NL]; Mezenhof 130, NL-1742 GN Schagen (NL).

(54) Title: DEVICE FOR INTRODUCING A RADIOACTIVE SOURCE INTO THE BODY

(57) Abstract

The invention relates to a device for introducing a source of radioactive radiation into the body for therapeutic applications, comprising a flexible cable (10) to be introduced into the body through a catheter and a capsule (12), for sealingly containing the source (14) of radioactive radiation. The capsule (12) comprises a thin-walled (17) tubular reservoir having an open end which is sealingly connected to the flexible cable (10) so that the capsule is coaxial to the flexible cable and having closed end (15) with a rounded-off external shape. The capsule accommodates a quantity of iridium-192 (14) of a capacity sufficient for therapeutic application. The radioactive source (14) of iridium-192 is provided within the capsule (12) in the form of a single bar.



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UNITED STATES DISTRICT COURT WESTERN DISTRICT OF LOUISIANA LAKE CHARLES DIVISION

INTERVENTIONAL THERAPIES, LLC

JUDGE TRIMBLE

VS.

MAG. WILSON

GUIDANT CORPORATION

NO. CV02-2130

GUIDANT'S RESPONSES TO IT'S FIRST SET OF INTERROGATORIES (NOS. 1-13)

Pursuant to Rules 26 and 33 of the Federal Rules of Civil Procedure, Defendant Guidant Corporation ("Guidant") objects and responds as follows to the First Set of Interrogatories of Plaintiff Interventional Therapies, LLC ("IT").

GENERAL OBJECTIONS AND QUALIFICATIONS

- 1. The information contained in these Objections and Qualifications and responses is provided in accordance with the provisions and intent of the Federal Rules of Civil Procedure, which are directed to the disclosure of requested non-privileged facts within the recipient's knowledge that may be relevant or lead to the discovery of relevant information. These objections and responses are made without waiving any rights or objections or admitting the relevance, materiality, or admissibility into evidence of the subject matter or facts contained in any interrogatory or Guidant's response thereto. Nothing herein constitutes an admission by Guidant relative to the existence or non-existence of any information or document.
- 2. Guidant objects to IT's discovery requests to the extent they purport to require

 Guidant to provide information beyond its possession, custody, or control, which Guidant cannot
 do.

- 3. Guidant objects to IT's Definitions and Instructions and to any IT discovery request to the extent IT seeks to impose on Guidant an obligati n not required by the Federal Rules of Civil Procedure.
- 4. Guidant objects to the discovery requests to the extent they seek information protected by the attorney-client privilege, the attorney-work-product doctrine, or any other applicable privilege, or that are otherwise immune or protected from discovery.
- 5. Guidant objects to the discovery requests to the extent that they seek information which is not relevant to the issues in this litigation or are not reasonably calculated to lead to the discovery relevant and admissible information.
- 6. Guidant objects to the discovery requests to the extent they contain numerous subparts and pose multiple questions.
- 7. To the extent the discovery requests call for the production of information without a date limitation, Guidant objects to the discovery requests as being overly broad, unduly burdensome, and call for information that is neither relevant nor calculated to lead to the discovery of relevant and admissible evidence.
- 8. Guidant objects to the discovery requests to the extent they prematurely seek information or documents that support Guidant's contentions at trial. To the extent Guidant responds to such discovery requests, it does so on the basis of its present understanding and without prejudice to its right to obtain and present at trial or in pretrial proceedings such additional information as may be acquired through investigation, discovery, or otherwise. Guidant expressly reserves the right to amend or supplement its responses to its discovery requests at any time.

- 9. Guidant objects to the discovery requests to the extent they call for the production of information of predecessors or successors in interest to allegedly include the Omnitron Corporations incorporated in the states of Delaware and Louisiana and Neocardia, or any agents, employees, officers, directors, attorneys, investigators, consultants and any other persons under the control of any of the foregoing entities.
- 10. These General Objections and Qualifications apply to all of IT's discovery requests. To the extent that the substance of these General Objections is repeated in response to specific discovery requests, such objections are repeated because they are particularly applicable to such discovery requests and are not to be construed as a waiver of any other General Objections applicable to information falling within the scope of such discovery requests.
- These responses are made solely for the purpose of this action. Each discovery request is subject to all objections as to competence, relevance, materiality, admissibility, and any other objections that would require the exclusion of any statement contained herein if such statement were made by a witness present and testifying in court. All such objections and grounds are reserved and may be interposed at the time of trial.
- 12. Guidant incorporates herein by reference its General Objections and

 Qualifications set forth in Guidant's Responses to IT's First Request for the Production of

 Documents and Things.

SPECIFIC OBJECTIONS AND RESPONSES

Subject to and without waiving its General Objections, which are incorporated herein by reference, Guidant objects and responds to IT's Interrogatories as follows:

Interrogatory No. 1:

Identify each Radiation Treatment Technology sold and or offered for sale by Guidant, by trade name, model number, reference number, product type and/or other applicable

designation thereof, including any patents which purportedly cover the system or any component thereof.

Response:

Guidant objects to this interrogatory as being overly broad, unduly burdensome, and seeking information that is not relevant to the issues in the case and not reasonably calculated to lead to the discovery of admissible evidence. As plaintiff, IT bears the burden of specifically identifying the products that it accuses of infringement. Guidant also objects to this interrogatory as being overly broad to the extent it seeks information concerning Guidant products other than the accused Galileo Intravascular Radiotherapy System. Furthermore, Guidant objects to this interrogatory as being unduly broad and vague in that it does not state the time period for which IT requests the information. Guidant also objects to term "cover" as being vague and indefinite; it is not clear what IT means when it refers to patents that "cover" systems or components.

Subject to the specific objections and General Objections and Qualifications, Guidant identifies the following sold by Guidant:

- 1. The GALILEO® Intravascular Radiotherapy System ("Galileo").
- 2. GALILEO III® Intravascular Radiotherapy System ("Galileo III").

Interrogatory No. 2:

For each Radiation Treatment Technology identified in response to Interrogatory 1, state whether Guidant contends that any of the Asserted Claims is not infringed. For each Asserted Claim that Guidant contends is not infringed by each such Radiation Treatment Technology, state the specific legal and factual bases for such contention, and state in detail any and all facts (including identifying specific elements of the claims that are not present in the Radiation

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Treatment Technology) that Guidant believes support such contention, and identify all persons having knowledge of same.

Response:

Guidant repeats its objections to Interrogatory No. 1. Guidant also objects to this interrogatory as being overly broad, unduly burdensome, and seeking information that is not relevant to the issues in the case and not reasonably calculated to lead to the discovery of admissible evidence. Guidant also objects to this interrogatory to the extent it imposes a burden not required by the Federal Rules of Civil Procedure, and to the extent it seeks attorney work product information. Guidant further objects to this interrogatory as being premature. In that regard, Guidant notes that IT has not yet identified what specific claims are allegedly infringed by which specific aspect of Guidant products, and has not informed Guidant of how IT is construing the claims. Nor has IT provided any discovery regarding the conception and development of the alleged invention, the alleged differences between the alleged invention and the prior art, or the meaning of the terms and phrases in the patent claims. Further, IT has not provided any information demonstrating it has any bases for asserting any claim of infringement against Guidant or what those bases are. Guidant has also not had the opportunity to depose the person IT alleges is the inventor of the patents-in-suit. Moreover, Guidant's investigation of the case and its consideration of the issues are ongoing.

Subject to the specific objections and General Objections and Qualifications, and reserving the right to supplement its response, Guidant identifies at least the following claims that are not infringed by the Galileo and Galileo III for at least the following reasons:

Regarding claim 1 of the '333 patent, the Galileo and Galileo III do not infringe for at least the reason that they do not perform the steps of: "attaching a treatment tube to the connector port of the afterloader; sensing a positive connection between the treatment tube and CONFIDENTIAL 5

ATTORNEYS' EYES ONLY

through the c nnector port and treatment tube and into the body of a patient until a treatment sit is reached; determining the distance said inactive treatment wire has advanced from said home site of said inactive treatment wire to the treatment site; transmitting said distance to the electronic controller; storing said distance in the electronic controller" and "advancing the radioactive source wire from a home site of the radioactive source wire through the treatment tube to the treatment site utilizing the distance sensed in said determining step."

Regarding claim 1 of the '614 patent, the Galileo and Galileo III do not infringe for at least the reason that they do not include "a flexible, hollow, elongated housing tube having an outer surface, an interior wall surface, a distal end, and a proximal end, said proximal end having an inner surface, said housing tube constructed from a material exhibiting little or no memory retention allowing said elongated housing tube to return to its original shape after being bent"; "a flexible backbone wire having a proximal end, said flexible backbone wire provided within said housing tube and constructed from material exhibiting little or no memory retention allowing said backbone wire to return to its original shape after it is bent"; "a sealing device provided within said housing tube"; and "a radiation device provided within said housing tube, said radiation device included within said sealing device."

Regarding claim 19 of the '614 patent, the Galileo and Galileo III do not infringe for at least the reason that they do not include "a flexible, hollow, elongated housing tube having an outer surface, an interior wall surface, a distal end, and a proximal end, said proximal end having an inner surface"; "a backbone wire having a proximal end, provided within said housing tube"; "a capsule inserted into said proximal end of said flexible elongated housing tube, said capsule

provided with a distal end"; "a radioactive device inserted into said capsule"; and "a plug which seals said proximal end of said housing tube."

Regarding claim 29 of the '614 patent, the Galileo and Galileo III do not infringe for at least the reason that they do not include "a flexible, hollow, elongated housing tube having an outer surface, an interior wall surface, a distal end, and a proximal end, said proximal end having an inner surface"; "a backbone wire inserted into said elongated flexible housing tube"; "a radiation device comprising a source of radiation and encapsulating material wherein said source of radiation is encapsulated in said encapsulating material to provide a sealed source of radiation, said sealed source of radiation provided with a distal end, said radiation device provided within said housing tube"; and "a plug which seals said proximal end of said housing tube."

Regarding claim 94 of the '956 patent, the Galileo and Galileo III do not infringe for at least the reason that they do not include a "a flexible housing; a flexible backbone wire having a first end and a rounded second end, said backbone wire encased within said housing; and means for emitting radiation within said housing and adjacent to said rounded second end of the flexible backbone wire."

Regarding claim 97 of the '956 patent, the Galileo and Galileo III do not infringe for at least the reason that they do not include "a flexible housing; a flexible backbone wire having a first end and a rounded second end, said backbone wire encased within said housing; and a radiation source adjacent to said rounded second end of the flexible backbone wire."

Regarding claim 1 of the '392 patent, the Galileo and Galileo III do not infringe for at least the reason that at least the following steps are not performed: "providing a thin, flexible tube, said tube having an outer surface, an interior surface, a distal end, a proximal end, and a lumen of a predetermined diameter"; "inserting a flexible backbone wire into the lumen of said

distal end of said tube for a predetermined distance to encase said flexible backbone wire within said flexible tube"; "inserting a radioactive core into the lumen f said proximal end of said tube until it abuts said flexible wire" and "sealing said distal end and said proximal end of said tube."

Regarding claim 20 of the '392 patent, the Galileo and Galileo III do not infringe for at least the reason that at least the following steps are not performed: "providing a thin, flexible tube, said tube having an outer surface, an interior surface, a distal end, a proximal end, and a lumen of a predetermined diameter"; "inserting a flexible backbone wire into the lumen of said distal end of said tube for a predetermined distance"; "inserting a capsule into the lumen of said proximal end of said tube until a closed end of said capsule abuts said flexible wire"; "inserting a radioactive core into said capsule"; and "sealing said distal end and said proximal end of said tube."

Guidant identifies the following individuals with knowledge of the operation of the Galileo and Galileo III:

- 1. Richard Calfee
- 2. Richard T. Thornton
- 3. Ken Bueche
- 4. John Edison
- 5. Anthony Bradshaw

Interrogatory No. 3:

For each Asserted Claim, state whether Guidant contends that the claim is unenforceable, and if so, state the specific legal and factual bases for such contention, state in detail any and all facts that Guidant believes support such contention, identify all documents, including but not limited to all prior art, concerning same and identify all persons having knowledge of such facts.

Response:

Guidant objects to this interrogatory to the extent it imposes a burden not required by the Federal Rules of Civil Procedure, and to the extent it seeks attorney work product information. Guidant further objects to this interrogatory as being vague and overly broad. Guidant also objects to this interrogatory as being premature for at least the reasons set forth in Guidant's response to Interrogatory No. 2. Subject to the specific objections and General Objections and Qualifications, and reserving the right to supplement its response, Guidant identifies the following bases for inequitable conduct:

All of the claims of the '333 patent are unenforceable by reason of the patentee's inequitable conduct in failing its duty of candor and good faith in dealing with the United States Patent and Trademark Office ("USPTO"), including the duty to disclose information material to patentability, and in particular, by failing to disclose prior art regarding radiation treatment and source wire technology, including the Mini-Loader Remote Afterloader; and the prior invention by others, including at least Dr. Michael H. Hayman and Anthony Bradshaw, which, upon information and belief, the applicant for the '333 patent was aware of during the prosecution of the '333 patent and withheld with an intent to deceive.

All of the claims of the '614 patent are unenforceable by reason of the patentee's inequitable conduct in failing its duty of candor and good faith in dealing with the United States Patent and Trademark Office, including the duty to disclose information material to patentability, and in particular, by failing to disclose prior art regarding radiation treatment and source wire technology, including U.S. Patent No. 5,199,939; Application Serial No. 08/057,322; the prior manufacture, use, and sale of source wires made from Nitinol; and the invention by others, including at least Anthony J. Bradshaw, which, upon information and belief, the applicant for the

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'614 patent was aware of during the prosecution of the '614 patent and withheld with an intent to deceive.

All of the claims of the '956 patent, which issued from an application claiming priority to the '614 patent, are unenforceable based on the inequitable conduct involved in procuring the '614 patent. The '956 patent is also unenforceable by reason of the patentee's inequitable conduct in failing its duty of candor and good faith in dealing with the United States Patent and Trademark Office, including the duty to disclose information material to patentability, and in particular, by failing to disclose prior art regarding radiation treatment and source wire technology, including the prior manufacture, use, and sale of source wires made from Nitinol; and the prior invention by others, including at least Anthony Bradshaw, which, upon information and belief, the applicant for the '956 patent was aware of during the prosecution of the '956 patent and withheld with an intent to deceive.

All of the claims of the '392 patent, which issued from an application claiming priority to the '614 patent and the '956 patent, are unenforceable based on the inequitable conduct involved in procuring the '614 patent and the '956 patent. The '392 patent is also unenforceable by reason of the patentee's inequitable conduct in failing its duty of candor and good faith in dealing with the United States Patent and Trademark Office, including the duty to disclose information material to patentability, and in particular, by failing to disclose prior art regarding radiation treatment and source wire technology, including the prior manufacture, use, and sale of source wires made from Nitinol; and the prior invention by others, including at least Anthony Bradshaw, which, upon information and belief, the applicant for the '392 patent was aware of during the prosecution of the '392 patent and withheld with an intent to deceive.

Subject t the specific objections and General Objections and Qualificati ns, Guidant will provide responsive information at an appropriate time pursuant to the Scheduling Order. At present, while reserving the right to supplement its response, Guidant identifies that the above contentions are supported by at least the following documentation including: instruction manuals for the Mini-Loader Remote Afterloader; a 510(k) for the Mini-loader Remote Afterloader filed with the FDA by Samuel Liprie in 1991; a 1991 invoice for the Mini-loader Remote Afterloader; an invention disclosure filed in the patent office in 1988 for an afterloader signed by Samuel Liprie and naming Samuel Liprie, Michael Hayman and Lee Roy Morgan as inventors; newspaper and journal articles relating a highly publicized incident concerning the failure of a Nitinol source wire that occurred in November, 1992; and a memorandum from Anthony Bradshaw to Samuel Liprie dated 12/14/1989.

(12)

Guidant believes that at least Samuel Liprie, the prosecuting attorneys (Herbert M. Bedingfield, Elizabeth R. Hall, Raymond E. Farrell, Russell R. Kassner, George Likourezos, Basam E. Nabulsi, Michael A. Cantor, and Mitchell B. Wasson), Anthony Bradshaw, Richard Thornton, Michael Hayman, Richard Calfee, and John Edison have some knowledge of these facts.

Interrogatory No. 4:

For each Asserted Claim, state whether Guidant contends that the claim is invalid, and state the specific legal and factual bases for such contention, and identify all documents, including but not limited to all prior art, concerning same and identify all persons having knowledge of such facts.

Response:

CONFIDENTIAL ATTORNEYS' EYES ONLY

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Guidant objects to this interrogatory to the extent it imposes a burden not required by the Federal Rules of Civil Procedure, and to the extent it seeks attorney work product information.

Guidant further objects to this interrogatory as being premature for at least the reasons set forth in Guidant's response to Interrogatory No. 2.

Subject to the specific objections and General Objections and Qualifications, Guidant will provide responsive information at an appropriate time pursuant to the Scheduling Order. At present, while reserving the right to supplement its response, Guidant identifies that at least one or more of the asserted claims of the asserted patents is invalid based on one or more of the following prior taken alone or in combination, including but not limited to: U.S. Patents Nos. 2,476,644; 3,351,049; 3,567,943; 4,861,520; 4,969,863; 5,030,194; 5,069,226; 5,084,001; 5,092,834; 5,103,895; 5,139,473; 5,163,896; 5,199,939; 5,230,348; 5,282,781; 5,454,794; 5,624,372; 5,807,231; 5,851,172; 6,283,910; and 6,506,145; International Publication Nos. WO/94/25106; WO 92/00776; WO 94/25106; prior devices by at least Nucletron, Omnitron, and Gamamed; and prior inventions by, *inter alla*, Anthony Bradshaw and Dr. Michael Hayman.

Interrogatory No. 5:

State the legal and factual basis for each of Guidant's affirmative defenses of inequitable conduct, and identify who allegedly knew about the references that Guidant claims were withheld from the United States Patent and Trademark Office, and state Guidant's basis for alleging that such person(s) were aware of those references and their alleged materiality prior to the issuance of the relevant Patent-in-Suit.

Response:

Guidant incorporates its response to Interrogatory No. 3, above.

CONFIDENTIAL ATTORNEYS' EYES ONLY

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Interrogatory No. 6:

State the legal and factual basis for Guidant's affirmative defenses f estoppel, laches and equitable estoppel.

Response:

Guidant objects to this interrogatory to the extent it imposes a burden not required by the Federal Rules of Civil Procedure, and to the extent it seeks attorney work product information. Guidant further objects to this interrogatory as being premature, for at least the reasons set forth in Guidant's response to Interrogatory No. 2. Subject to the specific objections and General Objections and Qualifications, Guidant will provide responsive information at an appropriate time pursuant to the Scheduling Order.

Interrogatory No. 7:

Identify all persons and parties involved in all attempts by Guidant, or anyone acting on behalf of Guidant, to purchase, license or otherwise obtain any rights or ownership interest in any of the Patents-in-Suit, state with particularity their role in such activity, and identify all documents relating thereto.

Response:

Guidant objects to this interrogatory to the extent that it is vague and indefinite. Subject to the specific objections and the General Objections and Qualifications, Guidant responds as follows. Even though Guidant is the rightful owner of the patents-in-suit, it is investigating whether there were any attempts by Guidant, or anyone acting on behalf of Guidant, to purchase or license any rights or ownership interest in any of the patents-in-suit.

Interrogatory No. 8:

Identify all persons knowledgeable f any study, review, analysis and/or comparison of any and/or all of the claims of the Patents-in-Suit, including but not limited to any non-infringement, invalidity or unenforceability analysis, consideration of alternative technologies and any attempts to copy, imitate or design around the technology disclosed and claimed in the Patents-in-Suit, and identify the results of such study, review, comparison, analysis, consideration or attempts to design around.

Response:

Guidant objects to this interrogatory as being overly vague and unduly broad. Guidant further objects to this interrogatory to the extent it imposes a burden not required by the Federal Rules of Civil Procedure, and to the extent it seeks attorney work product information and privileged attorney-client communications. Subject to the specific objections and General Objections and Qualifications, Guidant is not presently aware of any attempts to copy, imitate, or design around of any of the claims of the patents-in-suit that is not protected by the attorney-client privilege or work product doctrine.

Interrogatory No. 9:

Identify all persons involved in any efforts to design, test, develop, market and sell each Guidant Radiotherapy System, and state the person's title and role therein.

Response:

Guidant objects to this interrogatory as being overly vague and unduly broad as it encompasses virtually every Guidant Radiation Therapy employee.

Interrogatory No. 10:

Describe the circumstances under which Guidant first became aware f any of the Patents-in-Suit, and identify all documents concerning same and the person or persons who became aware of the Patents-in-Suit.

Response:

Guidant objects to this interrogatory as being unduly vague and overly broad. Guidant objects to this interrogatory as being premature for at least the reasons set forth in Guidant's response to Interrogatory No. 2.

Subject to the specific objections and General Objections and Qualifications, Guidant became aware of the '614 patent no later than the conclusion of Liprie v. Omnitron International, et al., Civil Action No. 95-14588. Guidant became aware of the '956, '333 and '392 patents no later than IT's transmittal of the Complaint in this action to Guidant.

Interrogatory No. 11:

For each of the Asserted Claims, identify the art to which Guidant contends the subject matter of the claim applies, and state Guidant's contention as to the level of ordinary skill in the art as of the time the claimed inventions were allegedly made.

Response:

Guidant objects to this interrogatory as being vague and indefinite. Guidant also objects to this interrogatory as being premature, for at least the reasons set forth in Guidant's response to Interrogatory No. 2. Subject to the specific objections and General Objections and Qualifications, Guidant will provide responsive information at an appropriate time pursuant to the Scheduling Order.

CONFIDENTIAL ATTORNEYS' EYES ONLY

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Interrogatory N . 12:

Identify all current and past Radiation Therapy Technology that embody, operate, perform, or execute any invention claimed by the patents-in-suit; state with particularity the invention(s) that is (are) embodied, operated, performed, or executed by each such Radiation Therapy Technology; and state the bases for Guidant's contention that each such product embodies, operates, performs, or executes an invention, including all facts, documents, and specific record support establishing the same.

Response:

Guidant objects to this interrogatory as being vague and indefinite. Guidant objects to this interrogatory as being premature for at least the reasons set forth in Guidant's response to Interrogatory No. 2. Subject to the specific objections and General Objections and Qualifications, and to the extent this interrogatory is understood, Guidant responds that none of Guidant's Radiation Therapy Technology embodies, operates, performs, or executes any invention claimed by the patents-in-suit.

Interrogatory No. 13:

With respect to each above Interrogatory, identify all persons providing information used to answer each of these Interrogatories, and identify the documents reviewed in preparation of an answer to the Interrogatory.

Response:

Guidant objects to this interrogatory to the extent that it is vague and indefinite. Guidant further objects to this interrogatory as seeking information protected by the attorney-client privilege and the attorney work product doctrine. Subject to the specific objections and the General Objections and Qualifications, Guidant responds that information obtained from one or more of the following people may have been used to answer one or more of the Interrogatories.

- 1. Richard Calfee
- 2. Richard T. Thornton
- 3. Ken Bueche
- 4. John Edison
- 5. Anthony Bradshaw
- 6. Michael H. Hayman

Dated: June 2, 2003

Respectfully submitted,

J. Michael Jakes Kathleen A. Daley Edward J. Naidich

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Attorneys for Defendant Guidant Corporation

VERIFICATION

I, Richard Calfee, Vice President, Radiation Therapy, authorized to make this verification on behalf of Guidant, hereby verify that I have read GUIDANT'S RESPONSES TO IT'S FIRST SET OF INTERROGATORIES (NOS. 1-13). Although I do not have personal knowledge of all the facts contained in GUIDANT'S RESPONSES TO IT'S FIRST SET OF INTERROGATORIES (NOS. 1-13), I hereby state that it is true to the best of my knowledge, information, and belief, and were made on the basis of information reasonably available to Guidant as of this date.

Dated: 4/2/03

Richard Calle

CERTIFICATE OF SERVICE

I, Michael L. Martin, hereby certify that on June 2, 2003, a true and correct copy of the foregoing Guidant's Responses To IT's First Set of Interrogatories (Nos. 1-13) was served by the indicated means to the persons at the addresses listed:

Via First Class Mail:

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